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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
DOWELL, PAUL THOMAS	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 05/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/757,356	LABAS ET AL.	
	Examiner	Art Unit	
	Paul Dowell	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *3-6 and 12-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,7-11 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 January 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/20/04,7/19/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of claims 1, 2, 7-11 and 19 (group I) and election of SEQ ID NO:17 in the reply filed on 3/27/2006 is acknowledged. The traversal is on the grounds that the Examiner has not established that a serious burden would result from a search of the invention groups together. Applicant argues that separate searches of the prior art would not be required upon examination of all the invention groups. This is not found persuasive because the search required for a complete examination of the full scope of the claims is a serious burden. A complete examination entails searching in various databases to determine the state of the art, to determine if utility and enablement requirements have been met and to determine the novelty of the claimed inventions. Such a search for a complete examination of the claimed nucleic acids, proteins, antibodies, transgenic cells, transgenic organisms, method of producing said proteins and method of employing said nucleic acids would not be entirely co-extensive as argued by Applicant. Further, it is reiterated that the SEQ ID NOs recited by claims 1-4 represent nucleic acid sequences with distinct structure and nucleic acid sequences with distinct structure necessarily entail non-coextensive searches. Thus, it is maintained that a complete examination of all the invention groups together would constitute a serious burden.

The requirement for restriction of 1/25/2006 is still deemed proper and is therefore made FINAL.

Claims 3-6 and 12-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 3/27/2006.

Claims 1, 2, 7-11 and 19 are under examination in the instant office action.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

> The oath or declaration is defective because:
> It does not identify the mailing address of each inventor. A mailing address is an address at which an inventor customarily receives his or her mail and may be either a home or business address. The mailing address should include the ZIP Code designation. The mailing address may be provided in an application data sheet or a supplemental oath or declaration. See 37 CFR 1.63(c) and 37 CFR 1.76.

Drawings

The drawings are objected to because Figure 7 is generally illegible and uninterpretable. For example, many of the single letter amino acid codes shown in the protein alignment cannot be deciphered. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being

amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (page 47, line 17). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. Appropriate correction is required.

The use of the trademarks has been noted in this application. For example, SMART™ (page 46, line 8). It should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and

every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

Claims 1, 2, 7-11 and 19 are objected to as being drawn to a non-elected invention. Specifically, claims 1 and 2 are drawn to nucleic acids comprising the nucleotide sequence set forth in SEQ ID NOs: 1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 25, or 27. Applicant's have elected SEQ ID NO:17 and as such, claims 1 and 2 are drawn to a non-elected invention. Claims 7-11 and 19 depend directly or indirectly from claim 1 and are likewise objected to as being drawn to a non-elected invention.

Claims 1 and 2 are objected to because the claim recites "residues" in association with nucleic acid sequences instead of --nucleotides--. Note that "residues" is an art-recognized term associated with amino acids. Examiner has interpreted claims 1 and 2 to mean --nucleotides-- instead of "residues".

For clarity, claim 9 should be amended to recite --a construct comprising a vector and ***the*** nucleic acid according to claim 1--, instead of "***a*** nucleic acid" (see also claims 8, 10(b) and 19).

Correction of the above is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 2, 7-11 and 19 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 1 and 2 are drawn to a nucleic acid, which reads on a product of nature (e.g. a chromosome *in situ*). This rejection may be overcome if the instant claims are amended to indicate the hand of the inventor, for example the insertion of --isolated-- or –purified-- in connection with said nucleic acid to identify a product not found in nature (see MPEP § 2105). Claims 7-11 and 19 depend directly or indirectly from claim 1 and are likewise rejected under 35 USC § 101. It is noted that although claim 8 recites, "[A]n isolated nucleic acid", claim 8 also recites, "or mimetic thereof".

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Claims 1, 2, 7-11 and 19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

An isolated nucleic acid comprising SEQ ID NO:17, wherein said nucleic acid encodes a functional fluorescent protein; a construct comprising a vector and said nucleic acid; an expression cassette comprising said nucleic acid; a host cell comprising said expression cassette; and a kit comprising said nucleic acid,

does not reasonably provide enablement for:

Any nucleic acid that is substantially the same as or identical to a nucleotide sequence of at least any 10 nucleotides in length of SEQ ID NO:17, any fragment of said nucleic acid; a construct comprising a vector and said nucleic acid; an expression cassette comprising said nucleic acid; a host cell comprising said expression cassette; and a kit comprising said nucleic acid.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

While determining whether a specification is enabling, one considers whether the claimed invention provides sufficient guidance to make and use the claimed invention, if not, whether an artisan would have required undue experimentation to make and use the claimed invention and whether working examples have been provided. When determining whether a specification meets the enablement requirements, some of the factors that need to be analyzed are: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples, and whether the quantity of any necessary experimentation to make or use the invention based on the content of the disclosure is "undue" (In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)).

Furthermore, the USPTO does not have laboratory facilities to test if an invention will function as claimed when working examples are not disclosed in the specification,

therefore, enablement issues are raised and discussed based on the state of knowledge pertinent to an art at the time of the invention, therefore skepticism raised in the enablement rejections are those raised in the art by artisans of expertise.

The instant claims are drawn to a nucleic acid having a sequence of nucleotides that is substantially the same as or identical to a nucleotide sequence of at least 10 nucleotides in length of SEQ ID NO:17, variants and fragments thereof (claims 1, 2, 7 and 8). The claims are further drawn to a construct comprising said nucleic acid (claim 9), an expression cassette comprising said nucleic acid (claim 10), a cell or the progeny of said cell comprising said expression cassette (claim 11) and a kit comprising said nucleic acid (claim 19).

The specification discloses that the nucleic acid of SEQ ID NO:17 encodes a *Montastraea cavernosa* green fluorescent protein (page 4, lines 30-31). The breadth of the instant claims is such that they read on any nucleic acid of at least 10 nucleotides with an unspecified degree of homology to SEQ ID NO:17 and any fragment of said nucleic acid. For example, the recitation of "substantially the same" in claim 1 conveys a high degree of breadth upon the claimed nucleic acid and reasonably encompasses a large number of variants of said nucleic acid with said unspecified degree of homology to SEQ ID NO:17 that may or may not retain functionality (e.g. function as a green fluorescent protein [GFP]). The specification discloses that the nucleic acid of SEQ ID NO:17 encodes a functional GFP (pages 48-49 and Figure 4) but the specification provides no specific guidance as to which "at least 10 nucleotides" of SEQ ID NO:17 would retain function. The specification discloses that GFP-like proteins all share a

conserved tertiary structure termed the "beta-can" and a chromophore that is required for functionality of said GFP-like proteins (pages 49-50). The art of record at the time of the invention teaches that said "beta-can" is composed of multiple beta-strands that are located throughout the entire structure of GFP-like proteins and that formation of said "beta-can" may require multimerization of individual GFP-like proteins **(Wiedenmann et al, Proceedings of the National Academy of Science, 97:14091-14096, 2000, IDS**, see page 14095: col. 1, paragr. 1 to col. 2, last line; page 14092, Fig. 1F; page 14095, Fig. 5; and entire document**)**. Further, Wiedenmann teaches that "[F]or GFP fluorescence the β-can structure is essential" (page 14095, col. 1, paragr. 1, lines 11-12). Still further, Carter et al **(Comparative Biochemistry and Physiology, Part C 138:259-270, 2004)** teaches that all known GFP-like proteins identified have the defining characteristics of the original GFP including "the general β-barrel shape, the void β-strand, the top and bottom caps, and the basic chromophore structure, location and orientation" (page 266, col. 2, paragr. 1, lines 5-12). Thus, the art of record at the time of the invention teaches that it would be unlikely, or highly unpredictable, that the claimed nucleic acid having a sequence of nucleotides that is substantially the same as or identical to a nucleotide sequence of at least 10 nucleotides in length of SEQ ID NO:17 would encode a functional GFP-like protein. Further, the breadth of the instant claims encompasses nucleic acids encoding proteins that would, for example, lack a chromophore, said chromophore also being required for the functionality of GFP-like proteins. The specification provides no specific guidance or working examples to allow

an artisan to determine which particular portion of the structure must be retained in order to maintain functionality as a fluorescent protein.

The specification lacks adequate guidance/direction to enable a skilled artisan to practice the claimed invention commensurate in scope with the claims. Furthermore, while recombinant and mutagenesis techniques are well known in the art, it is not routine in the art to screen large numbers of mutated proteins or fragments of proteins where the expectation of obtaining similar activity is unpredictable based on the instant disclosure. The amino acid sequence of a protein determines its structural and functional properties. The predictability of what mutations or deletion of which domains can be tolerated in a protein's sequence and result in certain activity/property is low and is very complex. The steps necessary to overcome such unpredictability is well outside the realm of routine experimentation, because accurate predictions of a protein's function from mere sequence data are limited. Thus, the general knowledge and skill in the art is not sufficient and the specification needs to provide an enabling disclosure.

Neither the specification nor the art of record at the time of the invention provides enabling support to make or use the invention commensurate in scope with the claims and an artisan would experience undue experimentation because of the lack of specific guidance. Such experimentation will be undue because of the unpredictability of the claimed nucleic acid encoding a functional fluorescent protein. Neither the specification nor the art of record at the time of the invention provides sufficient guidance to address these issues for an artisan to practice the claimed invention. Thus, limiting the scope of the claims to: an isolated nucleic acid comprising SEQ ID NO:17, wherein said nucleic

acid encodes a functional fluorescent protein; a construct comprising a vector and said nucleic acid; an expression cassette comprising said nucleic acid; a host cell comprising said expression cassette; and a kit comprising said nucleic acid, is proper.

Written Description

Claims 1, 2, 7-11 and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are drawn to a nucleic acid having a sequence of nucleotides that is substantially the same as or identical to a nucleotide sequence of at least 10 nucleotides in length of SEQ ID NO:17, variants and fragments thereof (claims 1, 2, 7 and 8). The claims are further drawn to a construct comprising said nucleic acid (claim 9), an expression cassette comprising said nucleic acid (claim 10), a cell or the progeny of said cell comprising said expression cassette (claim 11) and a kit comprising said nucleic acid (claim 19).

The breadth of the instant claims is such that they read on any nucleic acid of at least 10 nucleotides with an unspecified degree of homology to SEQ ID NO:17. The specification discloses that the nucleic acid of SEQ ID NO:17 encodes a *Montastraea cavernosa* green fluorescent protein (page 4, lines 30-31). Thus, when considered in light of the specification, the instant claims are drawn to a large number of nucleic acid

molecules that encode a function fluorescent protein. However, the specification only discloses the nucleic acid comprising the nucleotide sequence as set forth in SEQ ID NO:17 and does not disclose any mutants, variants or fragments thereof.

In analyzing whether the written description requirement is met for genus claims, it is first determined whether a representative number of species have been described by their complete structure. In the instant case, SEQ ID NO:17 is the only species whose complete structure is disclosed. While the genus encompasses a large number of variants and molecules that have different structure, the specification does not describe the complete structure of a representative number of species.

Next, then, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (i.e. other than nucleotide sequence), specific features and functional attributes that would distinguish different members of the claimed genus. In the instant case, there are no other disclosed relevant identifying characteristics, specific features or functional attributes of said species.

Applicants' attention is directed to the decision in *In re Shokal*, 113 USPQ 283 (CCPA 1957) wherein is stated:

> It appears to be well settled that a single species can rarely, if ever, afford sufficient support for a generic claim. In re Soll, 25 C.C.P.A. (Patents) 1309, 97 F.2d 623, 38 USPQ 189; In re Wahlforss et al., 28 C.C.P.A. (Patents) 867, 117 F.2d 270, 48 USPQ 397. The decisions do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases. Thus, in the case of small genus such as the halogens, consisting of four species, a reduction to practice of three or perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably larger number of reductions to practice would probably be necessary.

Further, Applicant's attention is directed to the final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

In conclusion, Applicant's disclosure of one species (i.e. SEQ ID NO:17) of the claimed broad genus is not deemed sufficient to reasonably convey to one skilled in the art that Applicant was in possession of the claimed broad genus at the time the application was filed. Thus it is concluded that the written description requirement is not satisfied for the claimed genus.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 7-11 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite for the recitation of "substantially the same" because it is unclear how to quantify this amount over a sequence that is at least 10 nucleotides in length from SEQ ID NO:17, wherein the sequence does not have to be contiguous. Additionally, the specification does not provide a definition as to what is intended, thus, the metes and bounds of the claim is indefinite. The dependent claims hereto are included because they do not rectify the instant deficiency.

Claim 7 is indefinite for the recitation of "a fragment of the nucleic acid", as it is unclear which nucleic acid is referred to. It is suggested that the claim is amended to recite "a fragment of ***a*** nucleic acid".

Claim 8 is indefinite for the recitation of "hybridizes under stringent conditions" as the claim does not provide the conditions considered to be "stringent" and the art recognizes that hybridization conditions can vary (e.g. the wash conditions can vary).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2 and 7 are rejected under 35 U.S.C. 102(a) as being anticipated by Lesser et al **(GenBank Accession AF406766, 2001)**.

Lesser teaches a nucleic acid having a nucleotide sequence that is 89% identical to the nucleotide sequence disclosed in the instant application as SEQ ID NO:17. Thus, Lesser anticipates the instant claims.

Claim 7 is rejected under 35 U.S.C. 102(b) as being anticipated by Singh et al **(Journal of Virological Methods, 86:121-129, 2000)**.

Singh teaches dNTPs (i.e. dATP, dCTP, dGTP and dTTP) as a reagent in a reverse transcription reaction to generate cDNA (page 123, col. 1, paragr. 1, lines 1-3). It is noted that claim 7 recites "[A] fragment of the nucleic acid according to Claim 1". Reasonably interpreted, claim 7 reads on single nucleotides. Thus, Singh anticipates the instant claim.

Claims 1, 2, 7-11 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Falkowski et al **(U.S. Patent 6,933,375)**.

Falkowski teaches a nucleic acid having a nucleotide sequence disclosed as SEQ ID NO:1 that is 48% identical to the nucleotide sequence disclosed in the instant application as SEQ ID NO:17. Falkowski teaches that the nucleic acid of SEQ ID NO:1 encodes a *Montastrea cavernosa* fluorescent protein (col. 2, lines 25-48). Falkowsi teaches a construct comprising a vector and the nucleic acid of SEQ ID NO:1 (claim 6) and teaches a host cell comprising said vector (claim 7). Falkowski teaches that said nucleic acid can be incorporated into an expression vector to encode a fluorescent protein fusion protein that can be used to detect expression of therapeutic proteins when said vector is administered to humans as part of a gene therapy regimen (col. 6, lines 48-65). Thus, Falkowski anticipates the instant claims.

Claims 1, 2, 7-11 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Lukyanov et al **(U.S. Patent 6,969,597)**.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Lukyanov teaches a nucleic acid having a nucleotide sequence disclosed as SEQ ID NO:3 that is 39% identical to the nucleotide sequence disclosed in the instant application as SEQ ID NO:17. Lukyanov teaches that the nucleic acid of SEQ ID NO:3 encodes a fluorescent protein (col. 4, lines 38-40). Lukyanov teaches a construct comprising a vector and the nucleic acid of SEQ ID NO:3 (col. 11, lines 31-55), expression cassettes comprising said nucleic acid (col. 11, line 56 to col. 12, line 16) and teaches host cells comprising said vector (col. 12, lines 35-49). Lukyanov also teaches kits comprising said nucleic acid (col. 30, lines 42-58). Thus, Lukyanov anticipates the instant claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 7-11 and 19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5-8 and 16 of copending Application No. 11/187,622. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 2, 7-11 and 19 of the instant application are drawn to a nucleic acid having a sequence of nucleotides that is substantially the same as or identical to a nucleotide sequence of at least 10 nucleotides in length of SEQ ID NO:17 (claims 1, 2, 7 and 8), a construct comprising said nucleic acid (claim 9), an expression cassette comprising said nucleic acid (claim 10), a host cell comprising said expression cassette (claim 11) and a kit comprising said nucleic acid (claim 19). SEQ ID NO:17 is disclosed as a nucleic acid encoding a *Montastraea cavernosa* green fluorescent protein.

Claim 1 of '622 is drawn to a nucleic acid that encodes a non-aggregating chromo- or fluorescent mutant of an aggregating *Cnidarian* fluorescent protein or mutant thereof. *Montastraea cavernosa* is a *Cnidarian* (see page 2, lines 1-14 of the instant specification) and as such claim 1 of '622 is encompassed by claims 1, 2, 7 and 8 of the instant application. Further, claims 5-8 and 16 of '622 are drawn to a fragment of said

nucleic acid (claim 5), a construct comprising said nucleic acid (claim 6), an expression cassette comprising said nucleic acid (claim 7), a host cell comprising said expression cassette (calim 8) and a kit comprising said nucleic acid (claim 16).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusions

No claims are allowed.

If Applicants should amend the claims, a complete and responsive reply will clearly identify where support can be found in the disclosure for each amendment. Applicants should point to the page and line numbers of the application corresponding to each amendment and provide any statements that might help to identify support for the claimed invention (e.g. if the amendment is not supported *in ipsis verbis*, clarification on the record may be helpful). Should Applicants present new claims, Applicants should clearly identify where support can be found in the disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Dowell whose telephone number is 571-272-5540. The examiner can normally be reached on M-F, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram R. Shukla, can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Anne-marie Falk

ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER

Paul Dowell
Art Unit 1632